Rec'd PCT/PTO 11 MAY 2005

23 MAR 2005
WIPO PCT

专利合作条约

PCT

专利性国际初步报告
（PCT 第II章）
(PCT 36 和细则 70)

申请人或代理人的档案号 IEC030028PCT	关于后续行为　参见 PCT/IPEA/416 表	
国际申请号 PCT/CN03/00949	国际申请日(日/月/年) 11. 11 月 2003 (11.11.2003)	优先权日(日/月/年) 12.11 月 2002 (12.11.2002)
国际专利分类(IPC)或者国家分类和 IPC 两种分类 IPC^7　C07F9/6561；A61K31/675; A61P31/12		
申请人 天津市金士力药物研究开发有限公司 等		

1. 本报告是国际初步审查单位根据条约 35 做出的国际初步审查报告，并依照条约 36 将其传送给申请人。

2. 本报告共计 4 页，包括扉页。

3. □ 本报告还有附件，
   - a. □ (传送给国际局和申请人)共计 ______页，包含
     - □修改后的并且作为本报告基础的说明书修改页、权利要求书修改页和/或附图修改页，和/或对本国际初步审查单位所做出的更正页(见 PCT 细则 70.16 和行政规程 607)。
     - □国际初步审查单位认为修改超出原始公开范围的废除页，参见第 I 栏第 4 项和补充栏。
   - b. □ （传送给国际局）共计（指明电子载体的类型和数量）______，包含有在与序列表有关的补充栏中指明的计算机可读形式的序列表和/或与其相关的表格。（行政规程 802）

3. 本报告包括关于下列各项的内容：

- I ☒ 报告的基础
- II □ 优先权
- III □ 不做出关于新颖性、创造性和工业实用性的意见
- IV □ 缺乏发明的单一性
- V ☒ 按条约 35(2)关于新颖性、创造性或工业实用性的理由；支持这种意见的引证和解释
- VI □ 引用的某些文件
- VII □ 国际申请中的某些缺陷
- VIII ☒ 对国际申请的某些意见

提交要求书的日期 01. 4 月 2004 (01.04.2004)	完成本报告的日期 08. 3 月 2005 (08.03.2005)
中华人民共和国国际知识产权局 IPEA/CN 中国北京市海淀区西土城路 6 号(100088) 传真号：(86-10) 62019451	授权官员 肖瑛印 电话号码　(86-10)－62085253

专[illegible]国际初步报告

国[illegible]请号
PCT/CN03/00949

I. 报告的基础

1．关于所使用的语言，除本项下另有说明外，本书面意见基于的语言为提交本国际申请时所使用的语言。

□本书面意见基于原始语言的使用后述语言之译文 ____________，
这种语言是

□ 为了国际检索而提交的译文所使用的语言（细则 12.3 和 23.1（b））。
□ 为了国际申请的公布而提交的译文所使用的语言（细则 12.4）。
□ 为了国际初步审查而提交的译文所使用的语言（细则55.2和/或55.3）。

2．关于国际申请中各个部分，本报告基于（申请人为答复受理局根据条约 14 所发通知而提交的替换页，在本报告中视为“原始提交”的文件，不作为本报告的附件）

☒ 原始提交的国际申请。

□ 说明书， 第____________页 原始提交的，
第____________页 ____________初审单位收到的，
第____________页 ____________初审单位收到的。

□ 权利要求， 第____________项， 原始提交的，
第____________项， 按条约 19 条修改的(附有说明)，
第____________项 ____________初审单位收到的，
第____________项 ____________初审单位收到的。

□ 附图， 第________页，原始提交的。
第________页*， ____________初审单位收到的，
第________页*， ____________初审单位收到的。

□ 序列表和/或相关表格——参见与序列表有关的补充栏。.

3．修改导致以下内容的删除：

□ 说明书， 第 ____________页
□ 权利要求， 第 ________ ____________项
□ 附图， 第 ________页， 图 ________
□ 序列表 *（具体说明）* ____________
□ 与序列表相关的表格 *（具体说明）* ____________

4．□ 由于本报告附件的(某些)修改，如下所列，被认为超出了原始公开的范围，如补充栏所示，因此本报告是按照没有修改的情况做出的(细则 70.2(c))。

□ 说明书， 第 ____________页
□ 权利要求， 第 ____________项
□ 附图， 第______页，图______
□ 序列表（具体说明） ____________
□ 与序列表相关的表格（具体说明） ____________

*如果第 4 项适用，一些或全部的文件页可能做出“废除”标记。

专利性国际初步报告

国际申请号
PCT/CN03/00949

V. 按条约 35 (2)关于新颖性、创造性或工业实用性的理由；支持这种意见的引证和解释

1. 意见

新颖性(N)	权利要求 1-10	是
	权利要求	否
创造性(IS)	权利要求	是
	权利要求 1-10	否
工业实用性(IA)	权利要求 1-10	是
	权利要求	否

2. 引证和解释（细则 70.7）

a. 本报告引用的文献：

D1 = CN- A- 1330547

D2 = WO- A- 9904774

b. 解释

D1 涉及一种阿德福韦酯晶体及其药物组合物，和结晶方法（见 D1 说明书第 3 页第 1 行至第 25 行，第 6 页第 3 行至第 15 行，第 23 页第 4 行至第 25 页第 10 行和实施例 1—7，10）。D2 披露了阿德福韦酯的 4 种结晶形态及其制备方法，还描述了含这些晶态的药物组合物。但这些对比文件与权利要求 1—10 中阿德福韦酯的晶态不同，因此权利要求 1—10 符合 PCT 条约第 33 条（2）的规定。

权利要求 1—10 与上述对比文件的区别仅在于阿德福韦酯的晶型不同。但本领域普通技术人员很容易制备这些权利要求所述的晶型，且所述权利要求与 D1 和 D2 中的晶型及其药物组合物相比，没有产生任何意想不到的技术效果。该晶型的制备方法也是常规的。因此权利要求 1—10 不符合 PCT 条约第 33 条（3）的规定。

权利要求 1—10 符合 PCT 条约第 33 条（4）的规定。

VIII. 对国际申请的某些评论意见

就权利要求、说明书和附图的清楚性，或者权利要求是否得到说明书的充分支持提出以下意见：

权利要求8制备步骤中的编号与说明书不符，不符合PCT条约第6条的规定。

Translation

TRANSLATION

PCT Application
PCT/CN2003/000949

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IEC030028PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/CN03/00949	International filing date *(day/month/year)* 11 Nov. 2003 (11.11.2003)	Priority date *(day/month/year)* 12 Nov. 2002 (12.11.2002)

International Patent Classification (IPC) or national classification and IPC

IPC^7 C07F9/6561 ; A61K31/675; A61P31/12

Applicant

TIANJIN KINSLY PHARMACEUTICAL CO., LTD. ET AL.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   - a. ☐ *(sent to the applicant and to the International Bureau)* a total of ______ sheets, as follows:
     - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
     - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   - b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) ______, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand 01. Apr. 2004 (01.04.2004)	Date of completion of this report 08. Mar. 2005 (08.03.2005)
Name and mailing address of the IPEA/ Facsimile No.	Authorized officer Xiaoying Telephone No. (86-10)-62085253

INTERNATIONAL PRELIM[illegible]Y REPORT ON PATENTABILITY

Interna[illegible] application No.
PCT/CN03/00949

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language ____, which is the language of a translation furnished for the purposes of:

   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   ☒ the international application as originally filed/furnished

   ☐ the description:

   pages ____ as originally filed/furnished
   pages * ____ received by this Authority on ____
   pages * ____ received by this Authority on ____

   ☐ the claims:

   pages ____ as originally filed/furnished
   pages * ____ as amended (together with any statement)under Article 19.
   pages * ____ received by this Authority on ____
   pages * ____ received by this Authority on ____

   ☐ the drawings:

   pages ____ as originally filed/furnished
   pages * ____ received by this Authority on ____
   pages * ____ received by this Authority on ____

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

   - ☐ the description, pages ____
   - ☐ the claims, Nos. ____
   - ☐ the drawings, sheets/figs ____
   - ☐ the sequence listing *(specify)*: ____
   - ☐ any table(s) related to sequence listing *(specify)*: ____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

   - ☐ the description, pages ____
   - ☐ the claims, Nos. ____
   - ☐ the drawings, sheets/figs ____
   - ☐ the sequence listing *(specify)*: ____
   - ☐ any table(s) related to sequence listing *(specify)*: ____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIM[illegible]RY REPORT ON PATENTABILITY

Interna[illegible] application No.
PCT/CN03/00949

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

D1 = CN- A- 1330547
D2 = WO- A- 9904774

D1 describes a crystal form of adefovir dipivoxil and its composition, and the method to prepare the crystal (See description page 3 line 1 - line 25, page 6 line 3 - line 15, page 23 line 4 - page 25 line 10, examples 1-7, 10). D2 discloses four crystal forms of adefovir dipivoxil and the method to prepare the crystals, also discloses the composition including those crystals (See the whole document). The crystal forms of adefovir dipivoxil in D1 and D2 differ from that presently claimed. Therefore, the subject-matters of claims 1-10 meet the requirement of Article 33 (2) PCT.

Preparation of such crystals as claimed can be performed by the skilled person in the art on the basis of routine experimentation. Therefore the subject-matters of claims 1-10 are obvious in view of D1 or D2. Claims 1-10 seem to lack inventive step, and do not meet the requirement of Article 33 (3) PCT.

Claims 1-10 meet the requirement of Article 33 (4) PCT.

INTERNATIONAL PRELI[illegible]ARY REPORT ON PATENTABILITY

Inte[illegible]nal application No. PCT/CN03/00949

Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The serial numbers in the technical features of claim 8 are not fully referred to in the description. Claim 8 is therefore not supported by the description as required by Article 6 PCT.